

Message

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**From:** Annette Bloomberg [annette.bloomberg@bayer.com]  
**Sent:** 12/19/2018 11:48:56 AM  
**To:** Benbow, Bethany [benbow.bethany@epa.gov]  
**CC:** Schmid, Emily [Schmid.Emily@epa.gov]; Kenny, Daniel [Kenny.Dan@epa.gov]; BCSReg\_Archive [esepamailbox@bayer.com]; Douglas Hines [douglas.hines@bayer.com]; BCSReg\_Archive [esepamailbox@bayer.com]; BCSReg\_Archive [esepamailbox@bayer.com]  
**Subject:** RE: EPA file symbol 264-RENG & 432-RANU  
**Attachments:** Rotam label\_083100-00040-20160602.pdf

Hi Beth:

I have attached Rotam's label. We also used this label as a reference when we were developing our Esplanade Sure label. It has the non-crop uses on the label.

Also, I have our CSFs being updated with Rotam and Adama rimsulfuron technical sources for Esplanade Sure and Rotam, Adama and DuPont for Alion Complete. Our specialist is updating them today. Once I receive them, I will submit via the portal and include the Formulator's Exemption forms with the submission.

Thank you so much for the explanation for when option #2 applies. It is clear now. I will share your explanation with our regulatory colleagues at our next group meeting.

Happy Holidays and thank you for your help and direction, greatly appreciated.  
Annette

Freundliche Grüße / Best regards,  
Annette M. Bloomberg, Ph.D.

Regulatory Affairs Manager – Vegetation Management  
Environmental Science



Science For A Better Life

Crop Science Division  
Bayer U.S. LLC  
2 T.W. Alexander Drive  
Research Triangle Park, NC 27709

Tel: +1 919 549-2608  
Mobile: +1 919 627-0498  
E-mail: [annette.bloomberg@bayer.com](mailto:annette.bloomberg@bayer.com)  
Web: <http://www.bayer.com>

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**From:** Benbow, Bethany <benbow.bethany@epa.gov>  
**Sent:** Tuesday, December 18, 2018 9:31 PM  
**To:** Annette Bloomberg <annette.bloomberg@bayer.com>  
**Cc:** Schmid, Emily <Schmid.Emily@epa.gov>; Kenny, Daniel <Kenny.Dan@epa.gov>; BCSReg\_Archive <esepamailbox@bayer.com>; Douglas Hines <douglas.hines@bayer.com>; BCSReg\_Archive <esepamailbox@bayer.com>  
**Subject:** RE: EPA file symbol 264-RENG & 432-RANU

Hi Annette,

Please see my responses in red font below.

Regards,

*Beth Benbow*

Beth Benbow  
Biologist, M.S.  
Risk Manager, Registration Division  
Office of Pesticide Programs  
Environmental Protection Agency

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**From:** Annette Bloomberg <[annette.bloomberg@bayer.com](mailto:annette.bloomberg@bayer.com)>  
**Sent:** Monday, December 17, 2018 11:13 PM  
**To:** Benbow, Bethany <[benbow.bethany@epa.gov](mailto:benbow.bethany@epa.gov)>  
**Cc:** Schmid, Emily <[Schmid.Emily@epa.gov](mailto:Schmid.Emily@epa.gov)>; Kenny, Daniel <[Kenny.Dan@epa.gov](mailto:Kenny.Dan@epa.gov)>; BCSReg\_Archive <[esepamailbox@bayer.com](mailto:esepamailbox@bayer.com)>; Douglas Hines <[douglas.hines@bayer.com](mailto:douglas.hines@bayer.com)>; BCSReg\_Archive <[esepamailbox@bayer.com](mailto:esepamailbox@bayer.com)>  
**Subject:** RE: EPA file symbol 264-RENG & 432-RANU

Hi Beth:

We are in the process of updating our CSF with Dupont's Rimsulfuron Technical (Reg. No 352-555; 99%) (this technical source does not cover terrestrial non-crop areas and therefore does not qualify for Formulator's Exemption for the proposed product, Esplanade Sure. It may be used with FE for Alion Complete); Adama's (85777-1; 99%) (this tech source covers all proposed uses of both proposed products and thus FE may be used with this tech for both proposed products) and an alternate CSF for Rotam's Rimsulfuron Technical (81598-14; 97.5%) (this tech source covers all proposed uses of both proposed products and thus FE may be used with this tech for both proposed products) .

Do you want me to send you the formulator's exemption forms with the CSFs through the portal or directly to you via email? (both would be preferable)

I am supposed to get the CSFs tomorrow. If I can get the CSFs submitted by Wednesday, will this allow the petitions to move forward? (yes, if you can also provide a current end-use rimsulfuron label that contains the requested non-crop uses.)

Also, may I keep the Cheminova rimsulfuron technical on the CSF, since we are asking FMC to amend the technical to add these uses to the tech label, and FMC has indicated that these uses are covered? No, not at this time if you intend on using Formulator's exemption to cover the generic data requirements. You may come back with an amendment to add that source once the uses have been approved on the FMC technical label. If however, you choose to use the cite-all option to cover generic data, you may use this tech. at this time. You just need to make offers to pay for all rimsulfuron data submitters on the data matrix and check the offer to pay box on your Certification with Respect to Citation of Data form 8570-34.)

Also, we used DuPont's Matrix SG label for the crop and ES non-crop uses. I have attached the label. I referenced this label in the cover letters, but I did not include the Matrix SG label in the submission. For future reference, should I include the reference label in the submission? (As long as the label is referenced in the cover letter and application, there is no need to include a copy of it. We use the most recently approved label in PPLS regardless.)

Also, I noticed that DuPont had a label amendment in May of 2018 where they removed the non-crop uses. We used the 2017 version as our reference and these uses were on the label. Our petitions were being submitted the same time this amendment was being approved. (Unfortunately, that is a consequence of continually changing labeling. We cannot use an old label for reference because there may be a good reason that those uses were removed. Since we do not have the time or resources to backtrack and determine the reasoning for those use deletions, we can only base the labeling of

the proposed products on the last approved label of the cited labels. For this reason, I will still need you to provide a most current approved end-use label for rimsulfuron that has all the proposed use sites for each of your proposed products. You may cite a different end-use rimsulfuron product for each proposed product if you cannot find one that has all the crop and non-crop uses.)

Also, could you please help me understand under what scenarios number 2 applies (highlighted below)? FMC directed that the uses of interest for Bayer could be covered under item 2 below even though the uses were not specifically listed on their technical label. (Item 2 highlighted below allows for the use of data citation with offer to pay for data covering uses not listed on the tech. source's label. For instance, a FE may cover the generic data for all but one of the proposed uses, so the registrant may submit, in addition to the FE, a data matrix listing those additional data with an offer to pay so that they may still use that source to formulate the product. In your case, the FE does not apply at all because the source does not have a single use site being proposed listed on its label currently. You could still use that tech as a source, but only if you pay for the generic data using cite-all and listing out all the data submitters with offers to pay on a data matrix.)

#### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Only for formulation into a herbicide for the following uses:

1. TERRESTRIAL FOOD CROPS - Corn, Potatoes and Tomatoes.
2. Uses for which USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration.
3. Uses for experimental purposes that are in compliance with USEPA requirements.

Formulators using this product are responsible for obtaining EPA registration for their formulated products.

Thank you so much, and I look forward to getting further direction from you regarding these petitions.  
Annette

Freundliche Grüße / Best regards,  
Annette M. Bloomberg, Ph.D.

Regulatory Affairs Manager – Vegetation Management  
Environmental Science



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Crop Science Division  
Bayer U.S. LLC  
2 T.W. Alexander Drive  
Research Triangle Park, NC 27709

Tel: +1 919 549-2608  
Mobile: +1 919 627-0498  
E-mail: [annette.bloomberg@bayer.com](mailto:annette.bloomberg@bayer.com)  
Web: <http://www.bayer.com>

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**From:** Benbow, Bethany <[benbow.bethany@epa.gov](mailto:benbow.bethany@epa.gov)>

**Sent:** Monday, December 17, 2018 8:38 PM

**To:** Annette Bloomberg <[annette.bloomberg@bayer.com](mailto:annette.bloomberg@bayer.com)>

**Cc:** Schmid, Emily <[Schmid.Emily@epa.gov](mailto:Schmid.Emily@epa.gov)>; Kenny, Daniel <[Kenny.Dan@epa.gov](mailto:Kenny.Dan@epa.gov)>; BCSReg\_Archive <[esepamailbox@bayer.com](mailto:esepamailbox@bayer.com)>

**Subject:** RE: EPA file symbol 264-RENG & 432-RANU

Hi Annette,

Unfortunately, we cannot make a regulatory decision based on somebody's word and/or memory. The R314 timeframe does not allow for us to hunt down data on behalf of the registrant. This information should be straight-forward and on the label of the technical product(s) being used to formulate the proposed end-use product when the registrant is claiming formulator's exemption.

If you cannot provide a different technical source that does include all of the proposed uses for both products or if you do not choose to use cite-all and make an offer to pay for all those generic data of rimsulfuron, then your applications are deficient.

You also still need to provide end-use labeling citations containing all the proposed use sites for each active ingredient as specified in the R314 category description. In this case, you have that for indaziflam, but not for rimsulfuron.

*Beth Benbow*

Beth Benbow  
Biologist, M.S.  
Risk Manager, Registration Division  
Office of Pesticide Programs  
Environmental Protection Agency

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**From:** Annette Bloomberg <[annette.bloomberg@bayer.com](mailto:annette.bloomberg@bayer.com)>  
**Sent:** Saturday, December 15, 2018 10:32 AM  
**To:** Benbow, Bethany <[benbow.bethany@epa.gov](mailto:benbow.bethany@epa.gov)>  
**Cc:** Schmid, Emily <[Schmid.Emily@epa.gov](mailto:Schmid.Emily@epa.gov)>; Kenny, Daniel <[Kenny.Dan@epa.gov](mailto:Kenny.Dan@epa.gov)>; BCSReg\_Archive <[esepamailbox@bayer.com](mailto:esepamailbox@bayer.com)>  
**Subject:** RE: EPA file symbol 264-RENG & 432-RANU

Hi Beth:

Attached are the updated data matrices for Alion Complete and Esplanade Sure. I have added the indaziflam generic studies at the beginning and the product specific studies at the end.  
I also included an email from FMC (who acquired Cheminova) referencing that the uses are covered with their technical (option #2 on their technical). FMC also said they would send in an amendment as a backup. I am checking with the regulatory manager to make sure that was completed. It may still be pending at the Agency.

Please let me know if you require any additional information.  
Thank you,  
Annette

Freundliche Grüße / Best regards,  
Annette M. Bloomberg, Ph.D.

Regulatory Affairs Manager – Vegetation Management  
Environmental Science



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Crop Science Division  
Bayer U.S. LLC  
2 T.W. Alexander Drive  
Research Triangle Park, NC 27709

Tel: +1 919 549-2608  
Mobile: +1 919 627-0498  
E-mail: [annette.bloomberg@bayer.com](mailto:annette.bloomberg@bayer.com)  
Web: <http://www.bayer.com>

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**From:** Benbow, Bethany <[benbow.bethany@epa.gov](mailto:benbow.bethany@epa.gov)>  
**Sent:** Thursday, December 13, 2018 7:46 PM  
**To:** Annette Bloomberg <[annette.bloomberg@bayer.com](mailto:annette.bloomberg@bayer.com)>  
**Cc:** Schmid, Emily <[Schmid.Emily@epa.gov](mailto:Schmid.Emily@epa.gov)>; Kenny, Daniel <[Kenny.Dan@epa.gov](mailto:Kenny.Dan@epa.gov)>  
**Subject:** RE: EPA file symbol 264-RENG & 432-RANU  
**Importance:** High

Thanks Annette.

I am also looking at Esplanade Sure (432-RANU) and it appears to have the exact same deficiencies as Alion Complete Herbicide (264-RENG.)

The end-use rimsulfuron product you have cited does not contain a single use site in common with the proposed product.

With an R314, you need to provide an end-use product for each active ingredient (in this case, one for rimsulfuron and one for indaziflam) and both of the cited products must contain the all the use sites you are requesting on the proposed product.

In addition, none of the proposed use sites for Esplanade Sure show appropriate data compensation to support them based on the data matrix that only contains product chemistry and acute toxicity data requirements and a formulator's exemption form that only list a rimsulfuron technical that does not have a single use site in common with the proposed product.

If we can't get these use site/data compensation issues resolved by next Wednesday (December 18, 2018), I will have to follow up with formal 75-day deficiency letters for both pending products.

We are aware that this is being communicated to you late in the PRIA review. We just simply don't have the resources (warm bodies) currently and unfortunately I just received these yesterday. Once you have addressed these issues, the label reviews should go fairly quickly if the appropriate use restrictions, rates etc. have been taken from the most restrictive of the active ingredients. It is not possible to get further with the label review until we have cited rimsulfuron end-use products containing these proposed use sites to compare with.

Thanks for your attention to these matters.

*Beth Benbow*

Beth Benbow  
Biologist, M.S.  
Risk Manager, Registration Division  
Office of Pesticide Programs  
Environmental Protection Agency

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**From:** Annette Bloomberg <[annette.bloomberg@bayer.com](mailto:annette.bloomberg@bayer.com)>  
**Sent:** Thursday, December 13, 2018 3:49 PM  
**To:** Benbow, Bethany <[benbow.bethany@epa.gov](mailto:benbow.bethany@epa.gov)>  
**Subject:** Re: EPA file symbol 264-RENG; Alion Complete Herbicide

Hi Beth. Let me check into this. Thank you for calling this to my attention. Annette

Sent from my iPhone

On Dec 12, 2018, at 9:51 PM, Benbow, Bethany <[benbow.bethany@epa.gov](mailto:benbow.bethany@epa.gov)> wrote:

Hi Annette,

Thank you for agreeing to renegotiate the R314 PRIA for Alion Complete Herbicide. I have taken over the review of this proposed product registration package while Mindy Ondish is on detail, and I have a few questions about the use sites being proposed and data support provided for those uses.

It appears you have chosen to cover the generic data requirements for rimsulfuron by claiming formulator's exemption. Unfortunately, the technical you have used for this end-use product does not have a single use site in common with the proposed product. Therefore, a formulator's exemption does not apply in this situation. You would need to provide a data matrix that lists out all the generic data of rimsulfuron needed to cover the proposed use sites and make offers to pay for those data. Another option is to use a technical that does have all the same use sites as those being proposed. You would then need to also update the CSFs that are still under review.

Additionally, the data matrix provided only lists out the product specific data requirements (product chem. And acute tox), plus a public interest document. Although Bayer owns indaziflam, you will also need to list out the generic data supporting it on the data matrix since it technically does not qualify for formulator's exemption.

I also notice that the end-use rimsulfuron product being cited only lists "grapes" and not "Subgroup 13-07F including: Amur River Grape; Gooseberry; Grape; Hardy Kiwifruit, Hardy; Maypop; Schisandra Berry; cultivars varieties, and/or hybrids of these."

If you can provide adequate data support for the entire subgroup 13-07F, you will just need to provide an end-use product label for rimsulfuron that also includes the entire subgroup as well in order for us to consider allowing more than just "grapes."

Please let me know if further clarification is needed to correct these data compensation/use site issues. I am currently working part-time in the evenings outside of the office, so I can best be reached via email.

Regards,

*Beth Benbow*

Beth Benbow  
Biologist, M.S.  
Risk Manager, Registration Division  
Office of Pesticide Programs  
Environmental Protection Agency

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